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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte PETER KITE and DAVID HATTON

Appeal 2008-006032
Application 10/659,413
Technology Center 1600

Oral Hearing Held: Tuesday, April 21, 2009

Before DEMETRA MILLS, LORA GREEN and JEFFREY N. FREDMAN,
Administrative Patent Judges

ON BEHALF OF THE APPELLANTS:

ROBERT G. MUKAI, ESQ.
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The above-entitled matter came on for hearing on Tuesday, April 21, 2009, commencing at 9:30 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, 9th Floor, Hearing Room B, Alexandria, Virginia, before Priscilla S. Hopchas, Notary Public.

1 THE CLERK: Calendar number 28, appeal number 2008-6032,
2 Mr. Mukai.

3 JUDGE MILLS: Good morning.

4 MR. MUKAI: Good morning, Your Honor. Before I begin I'd like to
5 give our stenographer here a break on some of the compounds that we're
6 going to be talking about. I learned from the last time that we had this, that
7 it helps.

8 JUDGE MILLS: It does help, yeah, thank you. Okay, you have 20
9 minutes, you may begin when you're ready.

10 MR. MUKAI: Thank you very much, Judge Mills.

11 Before I talk about the merits of this appeal, I guess I could point out
12 that this particular application is a CIP of serial number ten series, 313,844,
13 that was a concurrent appeal in that parent application. That appeal panel
14 affirmed or rejected the Examiner, but I'd like to point out there are different
15 claims on appeal, there were different priorities, different issues. We of
16 course disagree with the decision of the panel, and we're preparing a request
17 for a rehearing as we speak right now.

18 This particular application relates to a serious problem in the art. And
19 that is, this relates to a composition for treating infections, particularly those
20 in hospitals where infection is a quite significant problem.

21 It's a matter of public record that in hospitals every year there are
22 200,000 deaths due to sepsis. This particular invention addresses that
23 challenge in the art, and is based on the discovery that tri- and tetra-sodium,
24 EDTA, ethylene diamine tetra-acetic acid, has a tremendous bacteriocidal

1 effect against a broad spectrum of microbes. And we've provided evidence
2 of this in the specification.

3 The claims recite a PH of at least 9.5, and that's a significant feature,
4 because contrary to other compositions in the art this is not a physiological
5 PH, and yet we have found that this is an effective PH against infection.

6 The bacteriocidal effect that we mentioned in many of our claims has
7 also significant meaning. This means that it kills all the bacteria in the
8 environment, and we have again provided evidence of that. This is not an
9 inhibitory type of thing where you just prevent further bacterial growth; this
10 actually kills bacteria.

11 It's designed for treating a variety of different materials, different
12 surfaces, and at claim 56 we specifically recite a lock flush composition,
13 which is important for catheters. You fill the catheter up with this type of
14 composition and it kills all the bacteria, and therefore permits the function of
15 the urinary or a dialysis type of catheter. That claims further recites that the
16 composition must be bio-compatible with these fine medical devices.

17 The claims also recite that the composition is sterile and
18 non-pyrogenic form, and this is an important recitation, because the sterility
19 of the composition means that there's no active bacteria present, and of
20 course that is important for a number of reasons.

21 However, the claims specifically also recite that the composition is a
22 non-pyrogenic form. This means it does not create fever in a patient, and
23 that's an important aspect to this --

24 JUDGE MILLS: How do you treat the composition to make it
25 non-pyrogenic; is it just autoclaving?

1 MR. MUKAI: No, what you do is, you make sure that it doesn't have
2 certain components in it that would create fever, whether --

3 JUDGE MILLS: I mean how do you do it in your specification?

4 MR. MUKAI: Well, what we do is, is we treat the composition in a
5 way that has components in it, we sterilize it, yes, that is absolutely true, but
6 the components that are added to this composition are selected such that it
7 doesn't have that adverse on the patient.

8 JUDGE MILLS: Okay, but where is that in your specification, and
9 what do you do in your specification to make it non-pyrogenic?

10 MR. MUKAI: The non-pyrogenic aspect of it, we do not specifically
11 say that you have to treat it that -- but there are certain compounds that will
12 create pyrogenicity, and I think that some of them we're actually going to
13 address in discussing the prior art.

14 JUDGE FREDMAN: So going to the prior art then, I think it's
15 prototype ten that they particularly rely on of Fahim; are any of the
16 compounds in that prototype pyrogenic?

17 MR. MUKAI: Yes, there are.

18 JUDGE FREDMAN: Which ones?

19 MR. MUKAI: PCMX and glutaraldehyde. As you will see actually
20 in Fahim, in example 11, they actually test the irritability on the eyes of
21 rabbits and they say yes, it does provide it. And it's again a matter of, all
22 you have to do is look in a chemical dictionary, and you will see that
23 glutaraldehyde is identified as an irritant.

24 The invention that we have made here --

1 JUDGE FREDMAN: But an irritant isn't necessarily -- I mean I don't
2 see the correlation there. A pyrogenic causes fever, and an irritant causes
3 distress. There's no necessary result that you're going to get a fever from
4 distress.

5 MR. MUKAI: We understand, Judge Fredman, that the pyrogenicity
6 of glutaraldehyde would result in a fever. We don't have technical evidence
7 of that, we admit that.

8 JUDGE FREDMAN: So there's no evidence in the record that
9 glutaraldehyde will cause a fever.

10 MR. MUKAI: That is correct.

11 JUDGE FREDMAN: Is there any evidence for any other compounds
12 in it that could cause a fever?

13 MR. MUKAI: No, there is not.

14 JUDGE FREDMAN: None on the record, no --

15 MR. MUKAI: None on the record, correct. All we have is the
16 dictionary and the medical evidence that these are significant irritants.

17 JUDGE MILLS: Well, do you have any evidence that an irritant can
18 be pyrogenic?

19 MR. MUKAI: Unfortunately not of record.

20 JUDGE MILLS: So we're just relying on your argument.

21 MR. MUKAI: Well, and the fact that, like you said, that the medical
22 evidence that is in the medical literature says that these are severe irritants.
23 And Fahim is definitely designed not for internal use. It's for washing of
24 hands.

1 JUDGE GREEN: Well, I understand that, but you have a comprising
2 claim, and you have a composition.

3 MR. MUKAI: Correct.

4 JUDGE GREEN: So the method of use, we're trying to find out how
5 your method of use is limiting the composition, and right now you're just
6 arguing things that you have no evidence of in the record.

7 MR. MUKAI: Well, there's no direct evidence of that, Your Honor.
8 What we have, again, is this, the medical evidence that we can point to, this
9 is the one that it is just --

10 JUDGE FREDMAN: We can accept that it's irritable, I don't think we
11 even need to argue that point, because you're not proving that you've ever
12 done that, that doesn't address the claim. So we're looking, you know, the
13 name of the game is the claim; the claim doesn't -- I don't think that it can't
14 be irritable, just that it can't be pyrogenic.

15 MR. MUKAI: That is correct. It does not say anything about
16 irritable, it says non-pyrogenic.

17 JUDGE FREDMAN: I mean, and it has to be sterile, and the method
18 of use, whether internal or external, it's reasonable to sterilize and --

19 MR. MUKAI: I would say that's probably correct, Your Honor, but
20 again, the composition of Fahim is certainly not designed for internal use.

21 JUDGE FREDMAN: Well, if it was the method that required internal
22 use that might carry weight.

23 MR. MUKAI: I'm sorry, Your Honor?

24 JUDGE FREDMAN: If it was a method claim that required internal
25 use, that might carry weight.

1 MR. MUKAI: Well, it's different.

2 JUDGE MILLS: Do you have any argument briefed about this, the
3 CMX and what was the other, the glutaraldehyde?

4 MR. MUKAI: Not glutaraldehyde; what we did was, we pointed out
5 two examples of 11 in either our reply brief or brief, we pointed out that that
6 discussed the irritability factor. So our invention has a number of substantial
7 advantages that is not recognized in the art.

8 It is, again, effective against a wide spectrum of microbes, which we
9 have provided evidence; it is safe for hospital personnel; one significant
10 feature is, it does not lead to antibiotic resistance, and of course MURSA,
11 epicillin resistant staphylococcus is a significant problem in the art. And the
12 tri- and the tetra-sodium EDTA have been shown to have superior properties
13 similar to other forms of EDTA.

14 As you've recognized, there are a couple of rejections, and there is one
15 principally related to Fahim. Fahim is an antimicrobial handwash that
16 contains three antimicrobial components. One of them is triclosan, the other
17 one is PCMX and the third one is glutaraldehyde.

18 These are the only identified antimicrobial agents in Fahim, and the
19 document specifically says that these should be present in the amount of
20 1.25 percent.

21 Now, clearly we agree that there is disclosure of EDTA compounds
22 and particularly tetra-sodium EDTA. But this is not used as an antimicrobial
23 component. It is used as what they call an enhancer, and there's no
24 recognition that this particular component provides any antimicrobial --

1 JUDGE FREDMAN: Does the federal circuit require recognition for
2 an enhancer --

3 MR. MUKAI: No, it does not.

4 JUDGE FREDMAN: So that's sort of not relevant.

5 MR. MUKAI: We're not talking in this one about an anticipation.

6 JUDGE FREDMAN: Well, inherently you can apply to 103.

7 MR. MUKAI: Yes, it can. The Examiner has, in making the
8 rejection, has admitted that Fahim does not teach a sterile non-pyrogenic
9 form, and for that purpose he has relied on the Wider composition. Now,
10 our position of course is that why would somebody take a composition of
11 Fahim and convert it into a sterile non-pyrogenic form when it's designed for
12 a handwash, and the design of Wider, which is for internal spaces or in one
13 aspect spray it onto the skin before surgical incision, is a different use and
14 different feature than the handwash composition of Fahim.

15 JUDGE MILLS: But we've already discussed that it may be
16 obviously sterilized, a composition that's being used on the outside of the
17 body, such as a handwash.

18 MR. MUKAI: Yes.

19 JUDGE GREEN: And you haven't provided any evidence that that,
20 the composition of Fahim, is not pyrogenic, so even if Wider might be a
21 slightly different use, why would it be unobvious to sterilize the composition
22 of Fahim?

23 MR. MUKAI: Well, Fahim does not require sterilization.

1 JUDGE GREEN: I understand that, but why would it be unobvious
2 to, I mean why wouldn't it be unobvious to sterilize the composition of
3 Fahim?

4 MR. MUKAI: Well, I think the --

5 JUDGE GREEN: Especially for storage, sale, you know, you don't
6 want microbes growing, you know --

7 JUDGE FREDMAN: Hospitals, doctors wash their hands before they
8 do anything.

9 MR. MUKAI: Well, I think with Fahim, because they have an
10 antimicrobial agent present, they're not so concerned about the sterilization,
11 and it's just like --

12 JUDGE GREEN: They may not be so concerned, but that doesn't
13 make it non-obvious.

14 MR. MUKAI: I think that you have to take a look at what the
15 function of the composition is, and say, if you take something like your
16 ordinary hand soap that has triclosan in it, how many of those have you ever
17 seen that says that we specifically sterilize; they do have an antimicrobial
18 agent in it, which they believe that if there's any type of incursion of bacteria
19 it's going to take care of it.

20 So they're not going to take the extra step to treat a composition to
21 place it in the form that our composition is going to be in, so that's in a
22 completely sterile form.

23 One point that I would like to raise right here is that even to the extent
24 that Wider, I'm sorry, Fahim has the EDTA in it, the Examiner has made
25 certain allegations or referred to prototype number ten, and has said that this

1 meets your weight limitations. In fact it does not. The amount that is used
2 in there is three percent, but it's only a 30 percent concentration of material.
3 And so that leads to 0.9 percent, and if you take a look at page 18 of Fahim,
4 that will clarify this misunderstanding.

5 The other thing in terms of the propriety of the combination of Fahim
6 with Wider is that --

7 JUDGE FREDMAN: Well, in fact actually at that point it says, he put
8 in the sodium at .9 percent active concentration; that's what you're saying?

9 MR. MUKAI: Yes, yes. It refers to a three percent, and then it says
10 0.9 percent active concentration.

11 JUDGE FREDMAN: And you expect you distinguish between active
12 concentration and whatever the regular concentration is?

13 MR. MUKAI: We define two percent weight per volume, and we
14 use --

15 JUDGE FREDMAN: Is his EDTA sodium three percent weight per
16 volume, or how is he making his?

17 MR. MUKAI: That is the active material, Your Honor.

18 JUDGE FREDMAN: Wait, when he says it's three percent, he must
19 mean three percent weight per volume; the rest is not active, I guess.
20 Otherwise three percent makes no sense.

21 MR. MUKAI: The specific one that is referred to in Fahim is that it
22 says that it's a 30 percent EDTA concentration, so that when you're talking
23 about three percent, it's really .9 percent active concentration.

24 JUDGE FREDMAN: But three percent what, three percent weight
25 per volume? What's the three percent?

1 MR. MUKAI: No, the three percent is of the total composition, so
2 you're adding three percent of a solution that contains 30 percent by weight
3 of the tetra-sodium EDTA.

4 JUDGE FREDMAN: I see.

5 JUDGE GREEN: I'm just having trouble finding this argument in
6 your brief or your reply brief. Can you tell me where it is?

7 MR. MUKAI: I don't know if we specifically referred to this weight
8 amount, but I know that the Examiner referred to it in the Examiner's
9 Answer.

10 JUDGE FREDMAN: And doesn't Fahim say according a preferred
11 composition according to the present is about .024 to about eight percent by
12 weight of the EDTA sodium --

13 MR. MUKAI: Yeah, the broader range does include it, Your Honor.

14 JUDGE FREDMAN: So we have an overlapping range here.

15 MR. MUKAI: Yes, I just want to point out that the specific prototype
16 that the Examiner has relied on does not in fact lead to the range of
17 composition that we --

18 JUDGE FREDMAN: Well, in one example it doesn't, but in fact if it
19 hits the broader range, that completely encompasses it on the --

20 MR. MUKAI: There is no prototype or example within Fahim that
21 meets the weight limitation.

22 JUDGE FREDMAN: This is an obvious misrejection, and he
23 teaches --

24 MR. MUKAI: I agree, this is an obvious misrejection. If you take a
25 look, though, at the active ingredients of Wider, there is a complete

1 diversion from those of Fahim. There was not a single active component
2 that is common in it. In fact Wider doesn't even mention EDTA much less
3 the tri- and tetra-sodium EDTA that we are claiming.

4 With regard to the PH, Wider teaches a PH of about one to five. Of
5 course we're claiming a PH of at least 9.5, and even Fahim prefers one of
6 7.59.5, although admittedly the broader range is a little bit wider than that.

7 The other thing that we'd like to point out is dependent claims 58 and
8 59. These recite that the EDTA itself provides at least 50 percent of the
9 antimicrobial activity, and what we're saying with these particular claims,
10 which we've argued separately, is that the prior art does not meet this,
11 because the prior art, whether you're looking at Fahim or Wider, specifically
12 includes separate antimicrobial agents. And there is again, no --

13 JUDGE FREDMAN: But apparently it has some amount of EDTA,
14 which is providing some amount of antimicrobial activity. The Examiner
15 doesn't obviously have a laboratory in which he can test it, so you provided
16 evidence that a composition of things will not provide 50 percent of the
17 antimicrobial activity.

18 MR. MUKAI: Well, Fahim for example requires a certain amount of
19 active components --

20 JUDGE FREDMAN: Sure.

21 MR. MUKAI: -- of the -- and if you take a look at any of the
22 compositions that they actively describe, the amount of active ingredients,
23 even on a weight basis I believe is greater than the amount of the, the active
24 amount of the EDTA. And again --

1 JUDGE FREDMAN: But it doesn't tell you the activity. That just
2 tells you their amounts.

3 MR. MUKAI: Well, the EDTA isn't recognized as having any
4 antimicrobial activity. It's strictly there as a quote, enhancer.

5 JUDGE FREDMAN: But the issue, the recognition issue is what
6 actually it does.

7 MR. MUKAI: That is true, but we have nothing in Fahim that says
8 that this particular amount, whether it's used in any one prototypical
9 composition, would have any amount of antimicrobial activity that is greater
10 than the defined antimicrobial components, of which there are three.

11 So the other rejection that is primarily relied on by the Examiner
12 refers to the Kurginski reference. Kurginski is specifically designed for
13 treating toilets and similar sanitary facilities, and the composition has a
14 specific use of removing hard rock-like white or nearly white deposits which
15 is some kind of reaction product of urine, closely adhering fecal matter and
16 rust.

17 The Kurginski composition contains an alkanol, an alkanolamine, a
18 mixture of two or more lower ether alkanols and a chelating agent which can
19 be the tetra-sodium EDTA. The Examiner has said yes, I agree that this is
20 not a sterile non-pyrogenic form, but I think it would be obvious to package
21 it as such in accordance with the teachings of Fahim and Wider.

22 Here, this is not even designed to touch human skin, much less treat
23 infections and prevent infections from occurring. We're clearly taking the
24 position here that no one of ordinary skill in the art would take a toilet

1 treating composition of Kurginski and try to convert it into a sterile
2 non-pyrogenic form.

3 JUDGE FREDMAN: Is there any claim that it's only reducted using
4 the Kurginski --

5 MR. MUKAI: No, it's all combination of Kurginski, Wider and at
6 least Kurginski and Wider --

7 JUDGE FREDMAN: But Kurginski is separate, 103, from Fahim and
8 Wider. Is there anything that's rejected in Kurginski, Fahim, Wider, that's
9 not rejected in Fahim Wider?

10 MR. MUKAI: No. We also would refer again to independent claim
11 56, which relates to that composition. The one final issue right here is that
12 the Examiner has said that the flush composition is an intended use.
13 However, we again would refer your attention to the fact that the claim
14 specifically recites that this composition must be biocompatible with these
15 defined medical devices.

16 We do not believe that any of these compositions, whether it's Fahim
17 or Kurginski, would provide that type of biocompatibility. You're talking
18 about compositions again for hand wash or for cleaning toilets, and we
19 believe that it does not meet that recitation.

20 So based on our claims and the evidence we've provided, we believe
21 that our claims are patentable over the prior combinations that are present.

22 JUDGE MILLS: Very good, thank you for your time.

23 MR. MUKAI: Thank you very much, Your Honor.

24 (Whereupon, at 9:55 a.m., the proceedings were concluded.)